CHAPTER 7
HOSPITAL PHARMACY PRACTICE

[Prior to 2/10/88, see Pharmacy Examiners[620] Ch 12]

657—7.1(155A) Purpose and scope. Hospital pharmacy means and includes a pharmacy licensed by the board and located within any hospital, health system, institution, or establishment which maintains and operates organized facilities for the diagnosis, care, and treatment of human illnesses to which persons may or may not be admitted for overnight stay at the facility. A hospital is a facility licensed pursuant to Iowa Code chapter 135B. This chapter does not apply to a pharmacy located within such a facility for the purpose of providing outpatient prescriptions. A pharmacy providing outpatient prescriptions is and shall be licensed as a general pharmacy subject to the requirements of 657—Chapter 6. The requirements of these rules for hospital pharmacy practice apply to all hospitals, regardless of size or type, and are in addition to the requirements of 657—Chapter 8 and other rules of the board relating to services provided by the pharmacy.

657—7.2(155A) Pharmacist in charge. One professionally competent, legally qualified pharmacist in charge in each pharmacy shall be responsible for, at a minimum, the items identified in this rule. A part-time pharmacist in charge has the same obligations and responsibilities as a full-time pharmacist in charge. Where 24-hour operation of the pharmacy is not feasible, a pharmacist shall be available on an "on call" basis.

1. Ensuring that the pharmacy utilizes an ongoing, systematic program for achieving performance improvement and ensuring the quality of pharmaceutical services;
2. Ensuring that the pharmacy employs an adequate number of qualified personnel commensurate with the size and scope of services provided by the pharmacy. Drug dispensing by nonpharmacists shall be minimized and eliminated wherever possible;
3. Ensuring the availability of any equipment and references necessary for the particular practice of pharmacy;
4. Ensuring that a pharmacist performs therapeutic drug monitoring and drug use evaluation;
5. Ensuring that a pharmacist provides drug information to other health professionals and to patients;
6. Dispensing drugs to patients, including the packaging, preparation, compounding, and labeling functions performed by pharmacy personnel;
7. Delivering drugs to the patient or the patient's agent;
8. Ensuring that patient medication records are maintained as specified in rule 7.10(124,155A);
9. Training pharmacy technicians and supportive personnel;
10. Procuring and storing prescription drugs and devices and other products dispensed from the pharmacy;
11. Disposing of and distributing drugs from the pharmacy;
12. Maintaining records of all transactions of the pharmacy necessary to maintain accurate control over and accountability for all drugs as required by applicable state and federal laws, rules, and regulations;
13. Establishing and maintaining effective controls against the theft or diversion of prescription drugs, controlled substances, and records for such drugs;
14. Preparing a written operations manual governing pharmacy functions; periodically reviewing and revising those policies and procedures to reflect changes in processes, organization, and other pharmacy functions; and ensuring that all pharmacy personnel are familiar with the contents of the manual;
15. Ensuring the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy.

657—7.3(155A) Reference library. References may be printed or computer-accessed. A reference library shall be maintained which includes, as a minimum, one current reference from each of the following categories, including access to current periodic updates.

1. Iowa pharmacy laws, rules, and regulations.
2. A patient information reference such as:

- USP Dispensing Information, Volume II (Advice for the Patient);
- Professional's Guide to Patient Drug Facts by Facts and Comparisons; or
- Leaflets which provide patient information in compliance with rule 657—6.14(155A).

3. A reference on drug interactions such as:

- First DataBank's Evaluations of Drug Interactions;
- Hansten & Horn's Drug Interactions, Analysis & Management; or
- Drug Interaction Facts by Facts and Comparisons.

4. A general information reference such as:

- Facts and Comparisons;
- USP Dispensing Information, Volume I (Drug Information for the Health Care Professional); or
- AHFS Drug Information.

5. A drug equivalency reference such as:

- Approved Drug Products With Therapeutic Equivalence Evaluations (Orange Book);
- ABC – Approved Bioequivalency Codes; or
- USP Dispensing Information, Volume III (Approved Drug Products and Legal Requirements).

6. An injectable-drug compatibility reference such as:

- Betty Gahart's Intravenous Medications; or
- Trissel's Handbook on Injectable Drugs.

7. A drug identification reference such as:

- Mosby's GenRx;
- Identidex by Micromedix;
- Ident-a-Drug; or
- Other drug identification reference to enable identification of drugs brought into the facility by patients.

8. The readily accessible telephone number of a poison control center that serves the area.
9. Additional references as may be necessary for the pharmacist to adequately meet the needs of the patients served. For example, the treatment of pediatric patients and oncology patients would require additional references unique to these specialties.

657—7.4 and **7.5** Reserved.

657—7.6(124,155A) Security. The pharmacy shall be located in an area or areas that facilitate the provision of services to patients and shall be integrated with the facility's communication and transportation systems. The following conditions must be met to ensure appropriate control over drugs and chemicals in the pharmacy:

7.6(1) *Pharmacist responsibility.* Each pharmacist, while on duty, shall be responsible for the security of the pharmacy area, including provisions for effective control against theft of, diversion of, or unauthorized access to drugs or devices, controlled substances, records for such drugs, and patient records as provided in 657—Chapter 21. Policies and procedures shall identify the minimum amount of time that a pharmacist is available at the hospital pharmacy.

7.6(2) *Access when pharmacist absent.* Policies and procedures shall be established which identify who will have access to the pharmacy when the pharmacist is absent from the facility and the procedures to be followed for obtaining drugs and chemicals during that absence. When the pharmacist is absent from the facility, the pharmacy is closed.

7.6(3) *Locked areas.* All pharmacy areas where drugs or devices are maintained or stored and where a pharmacist is not continually present shall be locked.

7.6(4) *Verification by pharmacist.* When the pharmacy is open, patient-specific drugs or devices shall not be distributed prior to the pharmacist's final verification and approval.

7.6(5) *Drugs or devices in patient care areas.* Drugs or devices maintained or stored in patient care areas shall be in locked storage unless the patient care unit is staffed by health care personnel and the medication area is visible to staff at all times.

657—7.7 Reserved.

657—7.8(124,126,155A) Drug distribution and control. Policies and procedures governing drug distribution and control shall be developed by the pharmacist in charge with input from other involved hospital staff such as physicians and nurses, from committees such as the pharmacy and therapeutics committee or its equivalent, and from any related patient care committee. It is essential that the pharmacist in charge or designee routinely be available to or on all patient care areas to establish rapport with the personnel and to become familiar with and contribute to medical and nursing procedures relating to drugs.

7.8(1) *Drug preparation.* The pharmacist shall institute the control procedures needed to ensure that patients receive the correct drugs at the proper times. Adequate quality assurance procedures shall be developed.

a. All drugs dispensed by the pharmacist for administration to patients shall be in single unit packages if practicable. The need for nurses to manipulate drugs prior to their administration shall be minimized.

b. Pharmacy personnel shall, except as specified in policies and procedures, prepare all sterile products, including chemotherapy injections, continuous and intermittent intravenous preparations, and irrigation solutions, in conformance with 657—8.30(126,155A).

c. Pharmacy personnel shall compound or prepare drug formulations, strengths, dosage forms, and packages useful in the care of patients.

7.8(2) *Drug formulary.* The pharmacist in charge shall maintain a current formulary of drug products approved for use in the institution and shall be responsible for specifications for those drug products and for selecting their source of supply.

7.8(3) *Medication orders.* There shall be no manual or electronic transcribing of medication orders by nursing or clerical staffs except for their own records. Hospitalwide and pharmacy stand-alone computer systems shall be secure against unauthorized entry. The use of abbreviations and chemical symbols on medication orders shall be discouraged but, if used, shall be limited to abbreviations and chemical symbols approved by the appropriate patient care committee. All systems shall provide for review and verification by the pharmacist of the prescriber's original order before the drug is dispensed except for emergency use or when the pharmacy is closed.

7.8(4) *Stop order.* A written policy or other system concerning stop orders shall be established to ensure that medication orders are not inappropriately continued.

7.8(5) *Emergency drug supplies and floor stock.* Supplies of drugs for use in medical emergencies shall be immediately available at each nursing unit or service area as specified in policies and procedures. Authorized stocks shall be periodically reviewed in a multidisciplinary manner. All drug storage areas within the hospital shall be routinely inspected to ensure that no outdated or unusable items are present and that all stock items are properly labeled and stored.

7.8(6) *Disaster services.* The pharmacy shall be prepared to provide drugs and pharmaceutical services in the event of a disaster affecting the availability of drugs or internal access to drugs or access to the pharmacy.

7.8(7) *Drugs brought into the institution.* Policies and procedures shall be established governing the use of drugs brought into the institution. Procedures shall address identification of the drug and methods for ensuring the integrity of the product prior to permitting its use by the patient.

7.8(8) *Samples.* The use of drug samples within the institution shall be eliminated to the extent possible. Sample use is prohibited for hospital inpatient use. If the use of drug samples is permitted for hospital outpatients, that use of samples shall be controlled and the samples shall be distributed through the pharmacy or through a process developed in cooperation with the pharmacy and the institution's appropriate patient care committee, subject to oversight by the pharmacy.

7.8(9) *Investigational drugs.* If investigational drugs are used in the institution:

a. A pharmacist shall be a member of the institutional review board.

b. The pharmacy shall be responsible, in cooperation with the principal investigator, for providing information about investigational drugs used in the institution and for the distribution and control of those drugs.

7.8(10) *Hazardous drugs and chemicals.* The pharmacist, in cooperation with other hospital staff, shall establish policies and procedures for handling drugs and chemicals that are known occupational hazards. The procedures shall maintain the integrity of the drug or chemical and protect hospital personnel.

7.8(11) *Leave meds.* Labeling of prescription drugs for a patient on leave from the facility for a period in excess of 24 hours shall comply with 657—subrule 6.10(1). The dispensing pharmacy shall be responsible for packaging and labeling leave meds in compliance with this subrule.

7.8(12) *Discharge meds.* Drugs authorized for a patient being discharged from the facility shall be labeled in compliance with 657—subrule 6.10(1) before the patient removes those drugs from the facility premises. The dispensing pharmacy shall be responsible for packaging and labeling discharge meds in compliance with this subrule.

7.8(13) *Own-use outpatient prescriptions.* If the hospital pharmacy dispenses own-use outpatient prescriptions, the pharmacy shall comply with all requirements of 657—Chapter 6 except rule 657—6.1(155A).

657—7.9(124,155A) Drug information. The pharmacy is responsible for providing the institution's staff and patients with accurate, comprehensive information about drugs and their use and shall serve as its center for drug information.

7.9(1) *Staff education.* The pharmacist shall keep the institution's staff well informed about the drugs used in the institution and their various dosage forms and packagings.

7.9(2) *Patient education.* The pharmacist shall help ensure that all patients are given adequate information about the drugs that they receive. This is particularly important for ambulatory, home care, and discharged patients. These patient education activities shall be coordinated with the nursing and medical staffs and patient education department, if any.

657—7.10(124,155A) Ensuring rational drug therapy. An important aspect of pharmaceutical services is that of maximizing rational drug use. The pharmacist, in concert with the medical staff, shall develop policies and procedures for ensuring the quality of drug therapy.

7.10(1) *Patient profile.* Sufficient patient information shall be collected, maintained, and reviewed by the pharmacist to ensure meaningful and effective participation in patient care. This requires that a drug profile be maintained for each patient receiving care at the hospital. A pharmacist-conducted drug history from patients may be useful in this regard.

a. Appropriate clinical information about patients shall be available and accessible to the pharmacist for use in daily practice.

b. The pharmacist shall review each patient's current drug regimen and directly communicate any suggested changes to the prescriber.

7.10(2) *Adverse drug events.* The pharmacist, in cooperation with the appropriate patient care committee, shall develop a mechanism for the reporting and review, by the committee or other appropriate medical group, of adverse drug events. The pharmacist shall be informed of all reported adverse drug events occurring in the facility. Adverse drug events include but need not be limited to adverse drug reactions and medication errors.

657—7.11 Reserved.

657—7.12(124,126,155A) Drugs dispensed to patients as a result of an emergency room visit. In those facilities with 24-hour pharmacy services, only a pharmacist or prescribing practitioner may dispense any drugs to an outpatient, including emergency department patients. In those facilities without 24-hour pharmacy services, or those facilities without outpatient pharmacy services or when the facility's outpatient pharmacy is closed, the following procedures shall be observed in dispensing drugs:

7.12(1) *Patients examined in emergency room.* Drugs may be dispensed only to patients who have been examined in the emergency room.

7.12(2) *Accountability.* Drugs may be dispensed only in accordance with the system of control and accountability for drugs administered or dispensed from the emergency room.

a. The system shall be developed and supervised by the pharmacist in charge and the facility's emergency department committee, or a similar group or person responsible for policy in that department.

b. The system shall identify drugs of the nature and type to meet the immediate needs of emergency room patients.

c. Controlled substances maintained in the emergency room are kept for use by, or at the direction of, prescribers in the emergency room. In order to receive a controlled substance, a patient must be examined in the emergency room by a prescriber who shall determine the need for the drug. It is not permissible under state and federal requirements for a prescriber to see a patient outside the emergency room setting, or talk to the patient on the telephone, and then proceed to call the emergency room and order the administration of a stocked controlled substance upon the patient's arrival at the emergency room.

d. The pharmacist in charge is responsible for maintaining accurate records of dispensing of drugs from the emergency room.

7.12(3) *Prepackaging.* Drugs dispensed in greater than a 24-hour supply may be dispensed only in prepackaged quantities not to exceed a 72-hour supply or the minimum prepackaged quantity in suitable containers. Prepackaged drugs shall be prepared pursuant to the requirements of 657—22.3(126). Drugs dispensed pursuant to this subrule shall be appropriately labeled as required in subrule 7.12(4), including necessary auxiliary labels.

7.12(4) *Labeling.* At the time of delivery of the drug, the practitioner shall appropriately complete the label, such that the dispensing container bears a label with at least the following information:

a. Name and address of the hospital;

b. Date dispensed;

c. Name of prescriber;

d. Name of patient;

e. Directions for use;

f. Name and strength of drug.

7.12(5) *Delivery of drug to patient.* The practitioner, or a licensed nurse under the supervision of the practitioner, shall give the appropriately labeled, prepackaged drug to the patient or patient's caregiver and shall explain the correct use of the drug.

657—7.13(124,155A) Records. Every inventory or other record required to be kept under this chapter or other board rules or under Iowa Code chapters 124 and 155A shall be kept by the pharmacy and be available for inspection and copying by the board or its representative for at least two years from the date of such inventory or record unless a longer retention period is specified for the particular inventory or record.

7.13(1) *Medication order information.* Each original medication order contained in inpatient records shall bear the following information:

a. Patient name and identification number;
b. Drug name, strength, and dosage form;
c. Directions for use;
d. Date ordered;
e. Practitioner's signature or that of the practitioner's authorized agent.

7.13(2) *Medication order maintained.* The original medication order shall be maintained with the medication administration record in the medical records of the patient following discharge.

7.13(3) *Documentation of drug administration.* Each dose of medication administered shall be properly recorded in the patient's medical record.

These rules are intended to implement Iowa Code sections 124.301, 124.303, 124.306, 126.10, 126.11, 155A.6, 155A.13, 155A.27, 155A.28, 155A.31, and 155A.33 through 155A.36.

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